## REMARKS

The issues outstanding in the Office Action mailed May 11, 2001, are the requirement for Restriction and the rejections under 35 U.S.C. §112, §102 and §103. Reconsideration of these issues, in view of the following discussion, is respectfully requested.

**Requirement for Restriction**

The Examiner has maintained the requirement for restriction, subsequent to Applicants' traverse. The traversal is maintained, and appropriate action will be taken in due course.

**Rejection Under 35 U.S.C. §112**

Claims 1, 2, 4, 5, 8-18, 22-25 and 39 have been rejected under 35 U.S.C. §112, first paragraph. Reconsideration of this disclosure is respectfully requested. It is not seen on what basis the Examiner supposes that a separation step is "critical". Applicants respectfully submit that such a step is not essential to conducting the invention. It is assumed that the Office Action is supposing that unbound markers must be separated before the remnance of bound markers can be measured. The text, for example at the top of page 6 of the present application, makes it quite clear that this is unnecessary. Indeed, it is stated, in the second paragraph at page 6, that determination of the analyte can be done without separation. Thus, it is seen that this rejection is without basis, and withdrawal thereof is respectfully requested.

**Rejection Under 35 U.S.C. §102**

Claims 1, 2, 4 and 5 have been rejected under 35 U.S.C. §102(b) over JP '442 (TDK Corp.). Reconsideration of this rejection is respectfully requested.

As will be recalled, TDK teaches a method of determining the concentration of an antigen or antibody in a liquid sample, known in the art as an agglutination assay. Thus, the application does not anticipate, much less suggest, a method for determining magnetic flux density of non-agglutinated matter, *i.e.*, in a heterogenous assay. However, it is argued in the Office Action that the recitation of a heterogenous immunoassay is given no patentable weight "because the recitation occurs in the preamble." This is untrue. For example, claim 1 recites:

"a process for qualitative and/or quantitative detection of analytes in a liquid and/or solid phase heterogenous immunoassay, comprising determining remnant magnetization *in said immunoassay* ...".

Thus, the heterogenous immunoassay is recited in the body of the claim. Moreover, the claim has been amended for clarity, but the amendment does not change the scope of the claim, as discussed above. Thus, it is submitted that the objection raised in the Office Action is moot.

Claims 22-24 have also been rejected under 35 U.S.C. §102(b) over Cohen et al. Reconsideration of this rejection is also respectfully requested.

Cohen also does not disclose or suggest a heterogenous assay technique. Thus, as discussed above, this rejection is also moot.

**Rejection Under 35 U.S.C. §103**

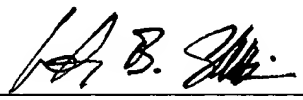
Claims 16-18 have been rejected under35 U.S.C. §103 over JP '442 taken with Cohen et al. As above, these references fail to suggest the present assays, and thus fail to suggest the presently claimed processes. Reconsideration of this rejection is therefore also respectfully requested.

**Double Patenting**

Claims 1, 9, 10 and 20 have been rejected under the doctrine of obviousness-type double patenting over claims 1, 15 and 20 of U.S. Patent 6,027,946. A terminal disclaimer is provided, and it is submitted that this rejection is moot.

The claims of the application are submitted to be in condition for allowance, and passage to issue is respectfully requested. However, should the Examiner have any questions or comments, he or she is cordially invited to telephone the undersigned at the number below.

Respectfully submitted,



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## VERSION WITH MARKINGS TO SHOW CHANGES MADE

**In the Claims:**

Claims 1 and 3 have been amended as follows:

**1. (Twice Amended)** A process for qualitative and/or quantitative detection of analytes in a liquid and/or solid phase heterogenous immunoassay, comprising determining remanence magnetization in said heterogenous immunoassay after addition to a sample of a stable or quasi-stable ferromagnetic or ferrimagnetic substances.

**3. (Twice Amended)** A process for qualitative and/or quantitative detection of analytes in a liquid ~~and~~ or solid phase heterogenous immunoassay, comprising

(i) labeling first structure-specific substances, with ferrimagnetic or ferromagnetic substances,

(ii) adding said magnetic labeled structure-specific substances to a sample that is to be measured,

(iii) magnetizing the sample to be measured with the aid of a magnetic field or suitable intensity that is applied from outside and,

(iv) measuring the remanence of the magnetization of bound structure-specific substances with the aid of magnetic field sensors after the external field is shut off.